DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M3016N

September 29, 1999

cc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99-55

Terrance O. Noble
Owner and CEO
Apothecary Products, Inc.
11750 12th Avenue So.
Burnsville, MN 55337

Dear Mr. Noble:

During our inspection of your drug repacking operation, located in Burnsville, Minnesota, our investigator found serious violations of the Current Good Manufacturing Practices (cGMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Aspirin and stool softener with laxative are drugs within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your stool softener is adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product is not in conformance with cGMP regulations.

The violations observed during our inspection include but are not limited to the following:

1. Failure to prepare batch production and control records for each batch of drug product produced [21 CFR 211.188]. In that there was no production record for the [redacted] bottles of aspirin labeled as stool softener with laxative.

2. Failure to conduct a 100% visual examination for correct labeling during or after completion of finishing operations for hand applied labels. Such examination shall be performed by one person and independently verified by a second person [21 CFR 211.122(g)(3)]. In that, the bottles containing aspirin labeled as stool softener with laxative were not examined to ensure the correct labeling was on the bottles.

3. Failure to quarantine the drug products before release by the quality control unit [21 CFR 211.142(a)]. In that aspirin labeled as stool softener was not quarantined before release by the quality control unit.

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and or injunction. This is official notification that FDA expects all your locations to be in compliance.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

In addition to your most recent recall, we note that you had a recall in 1997 regarding mislabeled [redacted] tablets and mislabeled [redacted] Aspirin. Also, in 1993 you had a recall regarding mislabeled Kelp Natural Iodine Tablets. Since your firm has a history of GMP problems regarding labeling. We believe it's prudent to have you meet with us in our Minneapolis Office. We have scheduled a meeting for Thursday, October 14, 1999 at 10:30 a.m. Also bring copies of documentation demonstrating that corrections have been made. If the meeting arrangements conflict with your schedule, please contact Compliance Officer Carrie A. Hoffman at (612) 334-4100 ext. 159 to make other arrangements.

Sincerely,

James A. Rahto
District Director
Minneapolis District

CAH/rfk